Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	**)**	
	)	
Amendment of Parts 2 and 95 of	**)**	**ET Docket No. 99-255**
the Commission's Rules to Create a	**)**	
Wireless Medical Telemetry Service	**)**	

To: The Commission

COMMENTS OF VITALCOM, INC.

VitalCom Inc., a manufacturer of medical telemetry systems and a member of the American Hospital Association Taskforce on Medical Telemetry, pursuant to Section 1.415 of the Commission's Rules, hereby files its comments on the Notice of Proposed Rule Making, released July 16, 1999, FCC 99-182 ("Notice") in the above-captioned proceeding.[1] By this Notice, the Commission proposes to amend Parts 2 and 95 of its Rules to allocate spectrum and to establish regulations for a new Wireless Medical Telemetry Service ("WMTS").

VitalCom Inc. strongly supports the Commission's proposal to allocate spectrum to WMTS with primary or co-primary status so that life-critical medical telemetry devices may operate on a blanket-licensed, interference-protected basis in the newly allocated bands. VitalCom commends the Commission for acting expeditiously in initiating this rule making and

[1]Members of the Taskforce included representatives of hospitals, clinics and other users of medical telemetry systems, manufacturers of medical telemetry devices, representatives of trade associations involved in the development of medical devices and the delivery of health care. A complete list of Taskforce members is included as Appendix I. While these recommendations necessarily reflect a consensus of the members of the Taskforce, any one of which may differ with particular recommendations, they benefit from the substantial diversity of interests, opinions and expertise of the Taskforce's members.

taking other proactive measures to protect against potential life-threatening incidents of harmful interference caused to wireless medical telemetry equipment.[2]

The Commission appropriately is planning now for the long-term spectrum requirements for WMTS. The near-term spectrum requirements of wireless medical telemetry equipment, however, cannot be ignored. Any rules adopted to facilitate the transition to WMTS expressly should authorize the continued use and manufacture of wireless medical telemetry equipment authorized for use in the Part 15 band. Said rules should incorporate at least a two-year transition period to the newly allocated spectrum for new product authorizations.

I. THE PROPOSED ESTABLISHMENT OF A PART 95 WIRELESS MEDICAL TELEMETRY SERVICE WOULD SERVE THE PUBLIC INTEREST

The Commission currently accommodates the use of biomedical telemetry devices on an unlicensed basis in the 174-216 MHz (VHF TV channels 7-13) and 470-668 MHz (UHF TV Channels 14-46) bands under Part 15 of its rules and at higher power levels in the 450-470 MHz band on a licensed basis under Part 90. Part 15 permits operation of biomedical telemetry devices with field strengths of 200 mV/m, measured at three meters, while hospitals or health care institutions that already hold Part 90 licenses in the Private Land Mobile Radio (PLMR) services are permitted to operate medical radio telemetry devices in the 450-470 MHz band without additional specific authorization with output powers up to 20 mW (330 mV/m at three meters).

Because of the introduction of digital television stations ("DTV") into TV broadcasting bands, some channels that were once unused for TV broadcasting, and thus available for wireless medical telemetry equipment operations, may now be used for DTV or low-power television

[2]As discussed in the Notice, the Commission has worked together with the Food and Drug Administration to help ensure that hospitals are notified before new digital television (DTV) stations come on the air to provide them with time to modify any medical telemetry equipment that operates on the same frequency. Notice at para. 9. The Commission also placed a freeze on the filing of certain applications for high power operation in the 450-470 MHz band that might interfere with existing users of wireless medical telemetry equipment. Id. at para 5.

broadcasting.[3] Moreover, medical telemetry equipment operating in the PLMR band under Part 90 of the Commission's rules potentially may be subject to increased interference due to the new channeling scheme adopted by the Commission in the 450-470 MHz PLMR band.[4] In initiating this proceeding, the Commission correctly recognized that this potential for increased interference to medical telemetry equipment must be addressed

The reliable use of wireless medical telemetry equipment is essential for health care providers to provide high quality and cost-effective care to patients with acute and chronic health care needs. Wireless biomedical telemetry devices are used in hospitals to transmit waveforms and other physiological data from patient measurement devices to patient monitoring, data distribution and storage systems. One of the main purposes of patient monitoring is the early detection of life-threatening physiologic developments so that appropriate and timely intervention can be rendered. Typical wireless devices may monitor ECG, oxygen saturation, blood pressure or respiration. The use of these devices offers patients rapid transition from procedure to procedure with continuous monitoring, mobility earlier in their recovery, as well as improved comfort while still being monitored for adverse symptoms. In addition, such devices allow more patients to be monitored by each health care worker, thus decreasing health care costs.

The profile of telemetry patient monitoring is expanding. Recovering cardiac patients represent the largest segment of patients being monitored by wireless telemetry; but more acute patients also are being monitored, as are the supplemental devices, such as ventilators and infusion pumps, that support these patients. In the future, these devices may be utilized for continuous monitoring of patients under emergency care, from field contact through rehabilitation. As the Commission correctly concluded, the use of such devices should be protected from interference in a broad array of health care facilities.[5]

[3] Id. at paras. 6-8.

[4] Id. at para. 4.

[5] Notice at para. 28.

According to surveys taken of hospitals by the Taskforce, many hospitals already have in excess of 300 patient-connected transmitting devices in use at one time. Those surveys also show that within 10 years, medium to large hospitals will use an *average* of 1,000 patient-connected transmitting devices. These devices will serve more types of acute patients, will monitor additional vital signs measurements and will be expected to perform reliably during procedures in the severe environments of EMI producing medical equipment. In this environment, it is imperative that the new WMTS be established promptly, using spectrum which is allocated to WMTS on a primary or co-primary, interference-protected basis. VitalCom commends the Commission for proposing such an allocation and urges expedited completion of this proceeding.

II. VITALCOM INC. ENDORSES THE COMMISSION'S PROPOSAL TO ALLOCATE WMTS A MINIMUM OF 14 MHz OF SPECTRUM

A. The Pending Spectrum Allocation Proposals.

As discussed in the Notice, the Taskforce submitted a report to the Commission dated April 15, 1999, in which it made specific recommendations of which frequencies should be allocated to WMTS on a primary basis.[6] The Taskforce recommended that a minimum allocation of 6 MHz of bandwidth be made available to WMTS for immediate use on a primary basis, with an additional allocation of at least 6 MHz for use on a primary basis over the next ten years. The Taskforce initially recommended that the following frequency bands, and a total of 14 MHz, be allocated for WMTS:

The Taskforce's April 1999 Recommendation

608-614	MHz (TV Channel 37)
1385 -1390	MHz
1432- 1435	MHz

[6] Report of the American Hospital Association Task Force on Medical Telemetry, April 15, 1999. See Notice at para. 10 and n. 14.

In the Notice, the Commission analyzed the current uses of, and the expressed potential interests in, the frequency bands recommended by the Taskforce as well as the bands adjacent to the recommended frequencies. Based on this analysis, the Commission proposed a minimum allocation of 14 MHz to WMTS but formulated two alternative options which it considered more suitable to protect WMTS from harmful interference.

FCC Proposed Option 1

608-614	MHz	(TV Channel 37)
1395 -1400	MHz	
1429 - 1432	MHz	

The Commission proposed 1395-1400 MHz in its Option 1 as an alternative to the 1385-1390 MHz band recommended by the AHA Taskforce in order to increase the frequency separation from, and thereby reduce the risk of interference by, U.S.-government radars operating below 1385 MHz. The Commission proposed the 1429-1432 MHz band as an alternative to the 1432-1435 MHz band recommended by the Taskforce but noted that the proposed band also was being investigated by Little LEO satellite operators for potential use for satellite feeder downlinks and was additionally requested for potential use for Part 90 PLMR services.[7]

[7]Notice at para. 22.

FCC Proposed Option 2

608-614 MHz (TV Channel 37)
1391 -1400 MHz

The Commission explained that its Option 2 would provide WMTS an additional 1 MHz of spectrum (a total of 15 MHz), although it recognized that the larger, contiguous upper band would be less useful for two-way WMTS communications than if the upper band allocation were split, as in Option 1.[8] The Commission noted that proposed Option 2 would resolve the potential conflict with Little LEO satellite downlinks in the 1429-1432 MHz band but would result in a 2 MHz overlap with a possible 1390-1393 MHz Little Leo satellite feeder uplink allocation and would also use parts of the frequency bands requested for future Part 90 PLMR services.

One significant factor could not be considered either by the AHA Taskforce in its initial recommendation or by the Commission in designing its proposed alternative options. That factor is the very recent consideration by Congress, as part of the National Defense Authorization bill for Fiscal Year 2000,[9] of a provision authorizing the U.S. Government to take back certain frequency bands, including the 1385-1390 MHz band, that earlier had been re-allocated for non-government use pursuant to the Balanced Budget Act of 1997.[10] Enactment of this provision into law obviously would preclude Commission adoption of the AHA Taskforce's initial recommendation of 1385-1390 MHz as one of the frequency bands allocated to WMTS. The AHA Taskforce, therefore, recognizes that it must make a revised frequency allocation recommendation for WMTS.

[8] Id. at para. 23

[9] S.1059, 106th Cong., 1st Sess. § 156 (c)(1)(B) (1999).

[10] Pub L. No. 105-33, Title III, 111 Stat. 251 (1997)

B. VitalCom, Inc. Favors The FCC's Proposed Option 1 Spectrum Allocation Alternative.

VitalCom applauds the Commission for its thoughtful analysis seeking to balance competing requests for frequency allocations with the need to protect wireless medical telemetry equipment from harmful interference. The Commission's proposed two options each correctly acknowledge the long-term need of WMTS to an allocation of 14 MHz of bandwidth or greater. The Commission for the most part also has identified the factors that must be considered in formulating a final allocation to the WMTS.

VitalCom endorses the Commission's proposal to adopt the Taskforce's initial recommendation to allocate 608-614 MHz to WMTS on a co-primary basis. This band has relatively low background noise because it is reserved for radio astronomy use. VitalCom cautions, however, that this 6 MHz allocation of lower band frequencies is not sufficient bandwidth by itself to support WMTS either in the short-term or the long-term. An allocation of spectrum in addition to 608-614 MHz is required for locations in the vicinity of radio astronomy "quiet zones" and where broadcasters' use of TV Channels 36 or 38 may interfere with WMTS use of Channel 37 frequencies. A preliminary review of coordination zones surrounding radio astronomy sites as proposed in § 95.1119 suggests that health care facilities in approximately 10 mid-size cities, including Cedar Rapids and Iowa City, Iowa, would be precluded from using the 608-614 MHz band for WMTS, in the absence of the concurrence of the director of the local radio astronomy observatory.

With respect to the upper band allocation, VitalCom strongly prefers non-contiguous (split) frequencies for reliable two-way command and control telemetry applications on WMTS systems (currently utilizing ISM bands), and the Commission's upper band spectrum allocation to WMTS should accommodate this need.

As the Commission recognizes, another important factor to be considered is whether and with whom WMTS will share its upper band allocation. As noted in the previous section, both

FCC proposed Options 1 and 2 propose an upper band allocation that includes spectrum which also is being investigated by Little LEO operators for satellite feeder links. After significant consideration of this problem, VitalCom has concluded that sharing of the WMTS upper band allocation with Little LEO operators is likely to prove problematic. The AHA Taskforce has had preliminary discussions with representatives of Little LEO satellite systems and, based on the limited information shared, VitalCom has determined that currently anticipated operating parameters for Little LEOs will make it very difficult, perhaps impossible, for low power WMTS devices to operate on an interference-free basis if they are sharing the spectrum with Little LEO operators. No less significantly, we have concluded that the problems of interference are likely to arise in both the 1390-1393 MHz (satellite feeder uplinks) or 1429-1432 MHz (satellite feeder downlinks).

At the power spectral flux density levels which the Little LEO operators currently anticipate needing for effective communications, downlink signals radiating across the country will likely interfere with low power WMTS devices throughout the nation. Under consideration by the Little LEOs is the use of 1429 – 1432 MHz for subscriber services. This application may be driving the power spectral flux density levels indicated. While it is possible that WMTS could ultimately coexist with Little LEO feeder downlinks at 1429-1432 MHz, it would be necessary to place power constraints on the Little LEO operations such that the safety and health of patients is not compromised.

Moreover, based on the discussions with the Little LEO representatives, it is even less likely that WMTS could share 1390-1393 MHz on a co-primary basis with proposed Little LEO feeder uplinks. Even under a "best-case" scenario — i.e., assuming that the frequency band for Little LEO feeder uplinks would be used exclusively from fixed locations which were relatively few in number and which were unlikely to be located in the immediate vicinity of authorized health care facilities — the fact that Little LEO uplink transmitters will be aiming their beams at the horizon will result in broad areas where interference levels are unacceptable to WMTS co-

channel users, and which will create a significant potential for interference at any health care facility that happens to lie in the line of a particular Little LEO uplink's view of the horizon. Depending on meteorological conditions, e.g. cloud scatter or atmospheric ducting, and terrain, e.g., a single dominant diffraction edge, it is quite possible that Little LEO uplinks will even create unacceptable levels of interference at health care facilities which are below the uplink's radio horizon.

VitalCom recognizes the efforts of the Little LEO operators to preserve the flexibility to obtain in the future an international frequency allocation which might include these bands. Unfortunately, to do so will essentially foreclose the availability of these channels for WMTS. VitalCom believes that the public interest would be much better served by allocating these frequencies for WMTS today, even if some of the benefits available from these Little LEO operations may be diminished if they are required to seek other frequencies in the future.

For the sake of completeness, however, VitalCom also recommends that the Commission consider one other alternative WMTS allocation, particularly since this option would avoid allocating the spectrum being investigated by the Little LEO operators:

The Taskforce's Alternative Proposal

608-614 MHz (TV Channel 37)

1394-1400 MHz

1427-1429 MHz[11]

This alternative proposal reflects the VitalCom's previously expressed preference for non-contiguous (split) frequencies in the upper band allocation in order to facilitate two-way communications on WMTS systems. Moreover, unlike FCC proposed Options 1 and 2, this alternative proposal minimizes the need to coordinate co-channel interference with potential Little

[11]If the Commission were to adopt this alternative upper band allocation for WMTS, it should authorize a maximum field strength of 740 mV/m, measured at 3 meters, the same field strength recommended by the Commission for its proposed options.

LEO operations in either the 1390-1393 MHz or 1429-1432 MHz bands. This alternative proposal also leaves room for an allocation for PLMR services near 1.4 GHz, especially if Congress does not enact the provision which would take back the 1385-1390 MHz band.

Because the 1427-1429 MHz band currently is lightly used for Government operations, this alternative proposal might be acceptable for WMTS as a primary allocation. However, VitalCom recognizes that this band also is licensed on a nationwide basis to a commercial company, Itron, Inc. for wireless meter reading systems. VitalCom understands that to date deployment of Itron's systems has been limited to clearly defined, specific geographic areas and that Itron's license has only secondary status. Itron, however, apparently has constructed systems using relatively high power in several large metropolitan areas, and these existing operations may need to be moved to different frequencies in order to avoid interference with WMTS's potential primary status in the 1427-1429 MHz band. VitalCom well understands the problems associated with potentially moving incumbent wireless operations to new frequencies, even when those operations enjoy less than primary status, and for that reason VitalCom suggests that the Commission consider this alternative proposal as it examines the spectrum sharing issues in the 1.4 GHz band.

III. VITALCOM, INC. GENERALLY SUPPORTS THE COMMISSION'S PROPOSED FREQUENCY COORDINATION AND EQUIPMENT REGISTRATION PROCEDURES BUT PROPOSES CERTAIN MODIFICATIONS

A. The Commission Should Appoint a WMTS Frequency Coordinator

As noted by the Commission,[12] the AHA Taskforce recommended the appointment of a frequency coordinator to maintain a database of all WMTS equipment in operation and to notify users of potential frequency conflicts. A database maintained by a frequency coordinator is

[12] Notice at para. 29.

essential if WMTS is to be "licenced-by-rule" rather than by individual applications for licenses. Without such a database, there would be no record of which frequencies are used by each health care facility and each device. Accordingly, VitalCom supports the Commission's proposal that all parties using WMTS equipment be required to coordinate their operating frequency and other technical operating parameters with a coordinator to be designated by the Commission.

VitalCom also supports the use of each of the criteria mandated by the Commission for certified frequency coordinators in other services, including providing coordination services on a non-discriminatory basis, processing applications in order of receipt, handling post-licensing conflicts, maintaining reasonable and uniform fees, establishing a single point of contact nationally, and facilitating the use of new technologies.[13] VitalCom also urges the Commission to appoint a coordinator which has a good familiarity with the operations of health care providers. To the extent that the American Hospital Association seeks to act as the designated coordinator, VitalCom believes that AHA will be able to satisfy each of the requisite criteria. Moreover, in light of its experience in the health care industry resulting from its representation of approximately 85 percent of the hospitals in the U.S., and its demonstrated past and current leadership role in promoting the interference-free operation of technologically advanced wireless medical telemetry devices, AHA is qualified to fulfill this role.

B. Because The Role of WMTS Frequency Coordinator Should Be To Notify Health Care Facilities of Potential Interference Rather Than To Assign Channels Or Set Priorities Among Them, The Commission Should Encourage The Registration of All Existing Part 15 Medical Telemetry Devices

The Commission proposed that, in order to avoid interference among WMTS devices, the equipment registered first in a geographic area would be entitled to protection over later-

[13] See Frequency Coordination in the Private Land Mobile Radio Services, 103 F.C.C. 2d 1093, 1119 (1986).

registered equipment.[14] The AHA Taskforce's April 1999 Report, however, expressly rejected the proposal to establish a first-in-time priority rule or to require the WMTS frequency coordinator to assign channels on a permanent basis to individual health care facilities. Rather, the Taskforce Report anticipated that the "licensing" database would provide a resource by which pre-existing and new "licensees" would be able to work together to use frequency planning to avoid instances of interference.

The Commission should recognize that the number and nature of WMTS licensees will be quite different than in most of the services in which the Commission authorizes the use of frequency coordinators. Unlike users of the PLMR services which apply for licenses primarily in order to advance their respective economic interests, WMTS licensees will be health care professionals dedicated to patient care and safety. In light of the potentially devastating impact of potential interference, all WMTS users will be highly motivated to cooperate in making new installations and, while operating any telemetry devices, to avoid being either the creators or the subjects of interference.

Moreover, granting any priority for being the first registered user of specific frequencies would induce a "gold rush" mentality that would encourage health care facilities to apply for as many frequencies as possible for their "protected service area." This result can be avoided if the registration of WMTS systems would entitle the user only to interference-free use of the registered devices, subject to the rights of similarly situated users of WMTS equipment operating in their area. First-in-time registration in the WMTS database should entitle the registrant only to protection from inadvertent interference from a subsequent registrant and the right to participate in the frequency coordination process with other health care facilities in their area, with limited deference to first-in-time operations and no deference to those who fail to register. The WMTS frequency coordinator should not assign channels or prioritize among health care facilities, but only alert the subsequent registrant of its need to coordinate with prior registrants. Mutual

[14] Notice at para. 29.

exclusivity should not be considered to exist until the prospective registrant has the opportunity to confirm that all frequencies in a given geographic area are being utilized.

To promote the interference-free operation of all wireless medical telemetry equipment, the Commission also should encourage existing users of Part 15 equipment to register with the WMTS frequency coordinator. This will benefit existing users, for example, by providing notice of their operations to subsequent users and, thus, protecting existing Part 15 users from new WMTS users of the same spectrum inadvertently interfering with their existing telemetry operations. Inasmuch as Part 15 users in 608-614 MHz must meet technical standards that are at least as stringent as the proposed WMTS standard for this band, there is no reason why current Part 15 users should be relegated to "second class" status as far as the frequency coordination database is concerned.

C. Allowing Immediate In-Home Use of WMTS Systems Would Complicate the Creation of the WMTS Frequency Coordination Database.

Until health care providers, equipment manufacturers, and whoever the Commission designates as WMTS frequency coordinator together gain experience in the frequency coordination of this new service, equipment in the WMTS bands should not now be authorized for in-home medical uses. In-home uses likely are to be transient, both in terms of geographic location and duration; and it is unclear how the frequency coordinator can ensure that its database will not become unreasonably cluttered from transient uses that soon become inactive. Thus, VitalCom recommends that for the time being WMTS equipment not be authorized for in-home medical uses. The Commission however, should express its willingness to revisit this issue in a future proceeding after some experience in frequency coordination of this service is gained and a showing can be made that in-home uses would be consistent with the intended purposes of WMTS.

D. WMTS Equipment Registrations Should Remain Effective Until Affirmatively Removed

The AHA Taskforce initially recommended that WMTS equipment registrations be effective for a term of five years and be subject to renewal for additional five-year terms.[15] Under the AHA Taskforce's initial recommendation, health care providers would be required to notify the frequency coordinator of any change in location or other operating parameters or when a device is taken out of service permanently. The Commission proposed to adopt these recommendations, except for the requirement that equipment registrations be renewed every five years. The Commission characterized the latter proposed requirement as "burdensome".

On further reflection, VitalCom agrees with the Commission that requiring renewal of equipment registrations every five years would be unreasonably burdensome. Health care facilities have been deploying wireless medical telemetry devices for many years without the requirement of renewing equipment registrations. It would be costly for health care facilities to set up new procedures to track the registration renewal dates for all the various types of WMTS devices they may utilize, and the price to be paid for any oversight in this ministerial task — removal from the WMTS frequency coordination database of the registration for a device that continues to perform life-protecting functions successfully — is too high.

VitalCom supports a requirement that health care facilities notify the WMTS frequency coordinator when their uses of registered WMTS frequency devices are being permanently discontinued, and it is confident that most facilities will handle this responsibility conscientiously. WMTS equipment registration, however, should remain effective until affirmatively removed by the heath care provider. In recognition of the fact that it is unlikely that the WMTS database will be absolutely up to date on all current WMTS operations, VitalCom would prefer to err on the side of caution by tolerating some degree of "clutter" in the WMTS database by retaining entries for devices that no longer are in service rather than unthinkingly purging the WMTS database of

[15] Notice, at para. 32.

devices that continue in useful operation simply because of an inadvertent failure of a health care facility to renew an equipment registration. In cases of potential interference between two WMTS devices, a new prospective user simply will bear the burden of identifying whether the prior-in-time use still is in operation and, thus, will require coordination with a new device. This procedure would be consistent with the proposed policy that the WMTS frequency coordinator act primarily as an information clearinghouse and not as the assignor of first-in-time, exclusive-use channel authorizations.

E. Access To The WMTS Frequency Coordination Database Should Be Open to All Parties

VitalCom supports opening access to the frequency coordination database to all interested parties without restriction. Open access may aid manufacturers and potential users to identify locations where certain devices no longer are being used and, therefore, responsibly can be deleted from the database. Moreover, as described above, if the Commission adopts VitalCom's proposal to allow, and encourage, the registration of medical telemetry equipment currently authorized under Part 15 of the Rules, the Commission and the health care community representatives may be able to develop mutually beneficial plans to minimize potential interference and to facilitate the transition to the new WMTS bands.

VitalCom also supports the Commission proposal not to require manufacturers to provide certain technical information to end users as part of the Declaration of Conformity process. [16] VitalCom agrees that manufacturers will provide this information as a routine matter, so that no requirement is necessary.

IV. THE COMMISSION SHOULD ADOPT THE OTHER SERVICE RULE RECOMMENDATIONS OF VITALCOM, INC.

[16] Notice at para. 39.

The Commission solicited comments on various other service rule proposals. VitalCom provides the following recommendations:

A. VitalCom Supports The Commission Proposal Not To Authorize WMTS Applications of Mobile Vehicles for Mobile to Mobile or Mobile to Fixed Site Communications but Proposes Patient to Mobile Communications within the WMTS

VitalCom is concerned about the potential misuse of WMTS if mobile to mobile or mobile to fixed site transmissions were allowed within the WMTS. However, VitalCom recognizes the benefit of patient to mobile communications based on the continuity of data collection throughout the patient health care cycle. Given the availability of WMTS compatible equipment, operating under the proper constraints, a patient may be placed on telemetry for monitoring in a wireless mode while first under emergency medical care. This time critical patient physiological data collected by the WMTS equipment would be available in the mobile vehicle immediately upon first care and could be provided to fixed sites such as the destination hospital via other means, e.g. PCS. Upon arrival at the fixed site the patient could be transferred seamlessly to the WMTS system of the fixed site. Any medical event occurring during that potentially stressful transition would be captured and properly utilized in the treatment. Furthermore, the duration of the transition would be decreased and the workload of the attending health care staff reduced. Given this scenario or others of similar context, the patient may be monitored via the same equipment throughout the duration of treatment.

VitalCom recommends that patient to mobile communications be authorized on a blanket-licensed basis, that it be subject to the same coordination requirements and that a decreased power level for WMTS operations within or adjacent to health care vehicles be established such that the potential for interference to local fixed site health care facilities is minimized.

B. VitalCom Supports The Commission Proposal Not To Authorize Video and Voice Transmissions Over WMTS Spectrum For the Time Being

The AHA Taskforce initially recommended that all types of information flows should be permitted in WMTS, including voice, data, video and telecommand, on both a unidirectional and bidirectional basis.[17] The Commission, however, expressed concern over allowing voice and video transmission in the WMTS. The Commission noted that allowing voice transmission could encourage the use of WMTS as a form of wireless intercom, rather than for its intended purpose of transmitting vital patient data, while video transmissions could occupy a significant portion of the available WMTS spectrum.[18]

VitalCom shares the Commission's concerns. It supports the proposal not to allow video transmissions on WMTS frequencies as long as it is clarified that the transmission of waveform information still is authorized. VitalCom also does not oppose the Commission's proposal not to allow voice transmissions on WMTS frequencies. However, considerable health care advantages can be achieved and many facilities have requested voice capability for that value. Under any of the proposed allocations, WMTS spectrum for data communications will be limited; and voice communications can be provided by equipment authorized under other rule parts.[19] As the use of this technology evolves, however, the Commission should consider revisiting this issue.

C. The Commission Should Adopt The Taskforce's Proposed Power Limit For The 608-614 MHz Band

In its report, the AHA Taskforce recommended field strength limits for WMTS transmitters both in the lower (608-614 MHz) and upper (1.4 GHz) frequency bands. The Commission noted that the Taskforce's proposed limit in the 608-614 MHz band is approximately 5 dB higher than the current Part 15 limit for equipment operating in this band and stated that the

[17] See Notice at para. 33.

[18] Id.

[19] The Taskforce emphasizes that it endorses the prohibition of voice communication using WMTS equipment but supports allowing the use of WMTS systems for two-way data communications for command and control telemetry applications.

Taskforce did not provide a justification as to why the limit should be increased.[20] Because of its concern that a higher limit could result in interference to radio astronomy, the Commission proposed to adopt the lower Part 15 field strength limits for the 608-614 MHz band.

VitalCom urges the Commission to adopt the AHA Task Force's initial recommended maximum field strength of 370 mV/m for the 608-614 MHz WMTS band, based on a maximum field strength of 200 mV/m at the boundary of the "quiet zones" of radio astronomy observatories. VitalCom provides justification for the higher power recommendation in Appendix I to these comments. Because authorization to register higher power equipment will result in lower costs and more reliable WMTS systems in the 608-614 MHz band for the majority of health care facilities, VitalCom proposes that higher power operations be authorized on a routine basis when properly coordinated with the affected observatory, if required, as defined in Appendix I.

V. THE COMMISSION SHOULD GRANDFATHER THE CONTINUED USE AND PRODUCTION OF WIRELESS MEDICAL TELEMETRY EQUIPMENT LAWFULLY MANUFACTURED FOR THE PART 15 BAND.

The Commission recognized that a transition period is necessary before requiring new equipment to be capable of operating in whatever frequency bands are allocated to WMTS. In its April 15, 1999, report, the AHA Taskforce estimated that manufacturers will require approximately three to four years to develop and market devices for WMTS bands and recommended a four year transition period.

In the Notice, however, the Commission states that it believes that four years is a longer transition period than necessary.[21] The Commission proposes that, beginning two years from the effective date of final rules in this proceeding, all medical telemetry equipment authorized must operate in the new frequency bands.[22] The Commission further proposes that medical telemetry

[20] Notice at para. 36.

[21] Notice at para. 41.

[22] Id.

equipment that already is in operation in the DTV bands as of that date may continue to be operated.[23]

VitalCom supports the abbreviated transition period to the extent that protections for the continued use of previously authorized equipment and of the currently authorized Part 15 frequencies also are adopted.

The Commission should clarify that only newly designed devices that are first subject to an equipment authorization after the second anniversary of a decision allocating new frequencies to WMTS must operate in the newly allocated spectrum.

The continued use of any device that was lawfully manufactured and in operation by the two-year transition deadline should be "grandfathered" permanently. Use of these existing devices should be authorized until the health care provider decides that they no longer are in acceptable working order or until they are being operated in an area where they are subject to objectionable interference from other, primary, licensed users. The health care industry simply cannot afford to replace the myriad of existing wireless telemetry devices until they have outlived their usefulness.

The continued manufacture of any wireless telemetry device that was lawfully manufactured prior to the expiration of the transition period also should be grandfathered, even if the device lacks the capability of operating in the WMTS bands. Lawfully manufactured telemetry devices which have proven themselves in the marketplace should not be required to be withdrawn from production. Moreover, devices lawfully operating under Part 15 prior to the transition deadline which merely are being re-authorized to reflect minor modifications (such as the replacement of obsolete components) should not be considered "newly designed" and also should be grandfathered for continued manufacture and operation outside the WMTS bands.

In sum, the Commission should allow the marketplace, not regulatory mandates, to drive the transition of wireless telemetry devices to the new Part 95 frequencies. If users continue to

[23] Id.

demand medical telemetry equipment operating outside the Part 95 frequencies, because DTV or PLMR deployments have not yet created unacceptable interference, the Commission should not stand in the way of such marketplace forces.

VI. CONCLUSION

For the foregoing reasons, the Commission should establish promptly a Wireless Medical Telemetry Service under Part 95 of its rules and adopt rules consistent with the views expressed herein.

Respectfully submitted,

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MEMBER OF THE AMERICAN HOSPITAL ASSOCIATION
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COMMENTS OF VITALCOM INC.

APPENDIX I

JUSTIFICATION FOR THE AHA RECOMMENDED POWER LIMIT FOR THE 608 – 614 MHZ BAND

The American Hospital Association Taskforce on Medical Telemetry (" the AHA Task Force" or "Task Force") recommended in its report a field strength of 370 mV/m for the 608 – 614 MHz band. The Commission noted that the Task Force's proposed limit in the 608-614 MHz band is approximately 5 dB higher than the current Part 15 limit for equipment operating in this

band.[24] Because of its concern that a higher limit could result in interference to radio astronomy, the Commission proposed to adopt the lower Part 15 field strength limits for the 608-614 MHz band.

VitalCom concurs with the concerns of the Commission and proposes a revised recommendation which properly protects the interests of the radio astronomy observatories while increasing the field strength limit for use in the 608 – 614 MHz band for the majority of the health care facilities. The proposed field strength would make available transmission at reduced cost and greater reliability. The basis for concern by VitalCom is the severity of the health care facility propagation environment, as observed in recently collected data, and the desire to affordably extend the coverage throughout the health care facility.

The intent of this appendix is to demonstrate the compatibility of radio astronomy, the revised FCC NPRM service rules and the Task Force recommended field strength in the 608 – 614 MHz band.

Radio Astronomy Observatory Protection

With respect to cochannel interference with radio astronomy, VitalCom proposes an adjustment to the authorized power in the vicinity of radio astronomy sites, such that the field strength at the radio astronomy site will not exceed the field strength which would be caused by a device operating in 608-614 MHz at the maximum field strength permitted by §15.242 at the boundary of the coordination zone specified in §15.242(e). To establish the additional protection radius required, VitalCom notes that §93.699 figures 10b and 10c both indicate a field strength attenuation of 0.5 dB/km in the range of 30-40 km, essentially independent of transmitting antenna height. Conservatively allowing for a field strength attenuation of only 0.33dB/km, an additional 8km of separation will provide the same protection for the VLBA stations as is provided by §15.242. Similarly, for the three other radio astronomy observatories, the same figures indicate an worst case attenuation (i.e., lowest attenuation per unit distance) of about

[24] Notice at para. 36.

.2dB/km in the 80-90 km range. An additional 15km radius would provide the same protection as is provided by §15.242.

In summary, then, VitalCom proposes that field strengths in excess of 200 mV/m at 3 meters require the same coordination as proposed in § 95.1119, but to a radius of 40 km for the VLBA stations and to a radius of 95 km for the other radio astronomy observatories noted in footnote US 311 of §2.106.

Justification for Higher Power

1) Cost

In a free space propagation environment, the 5 dB power increase will permit an increase in antenna spacing of 85% with no loss of performance (antenna spacing is based on received power which goes down with the square of distance). Thus, the number of antennas required to cover a given area of a health care facility will be reduced by approximately a factor of 3.5. Using a path loss exponent of 3 which is more realistic for indoor propagation rather than the free space value of 2, the number of antennas will still decrease by a factor of 2.25.

Vitalcom's experience with Part 15 biomedical telemetry systems in medium and large hospitals indicates that the antenna system's installed cost is typically on the order of 20-25% of the total installed cost of all the telemetry system hardware. Thus, the increased power level can be expected to reduce the total cost of a WMTS by about 10-15%. It is left as an exercise for the reader to determine whether this is a significant cost differential.

2) Reliability

Other things being equal, an increase of 5 dB in the transmitted power will result in a 5dB improvement in the receiver SNR per bit (E_b/N_0). From analytic results, this increase in SNR per

bit can be expected to reduce the BER by a factor of 5 to 30 assuming Additive White Gaussian Noise (AWGN)[25].

Various factors in the biomedical telemetry environment cause the observed BERs of biomedical telemetry system to be significantly less than the textbook values. However, the slope of the BER curve is not that much shallower than the textbook value.

A variety of data are included at the end of this Appendix to indicate the difficulty of the wireless propagation environment inside hospitals. While system link budgets vary from system to system, it cannot be reasonably argued that a higher available transmit power will not increase the WMTS system data transfer reliability.

[25] BER or $P_2 = \frac{1}{2}e^{-\rho b/2}$ for noncoherent (Binary) Frequency Shift Keying (FSK) , where ρ_b is the SNR per bit or E_b/N_0. $P_2 = \frac{1}{2}e^{-\rho b}$ for Differential Phase Shift Keying (DPSK). For a 5dB difference in ρ_b, the BER ratio is $e^{2.5dB}$ or about 5 for FSK and e^{5dB} or about 30 for DPSK. Other practical modulations for a WMTS tend to have BER curve slopes somewhere in this range, usually closer to the DPSK value for the more advanced modulations. See e.g., Proakis, *Communication Systems Engineering*, Sections 9.2 and 9.4

3) Efficiency of Modulation

The ever-increasing volume of data WMTS systems are expected to transport increases the importance of using efficient modulation approaches. Advances in microelectronics technology are making the application of these advanced modulations more practical. However, the modulations tend to require more power under equivalent circumstances.

Existing Part 15 and Part 90 biomedical telemetry transmitters most often use Binary Frequency Shift Keying (FSK or BFSK) modulation. Other existing systems of which VitalCom is aware use BPSK (Binary Phase Shift Keying), DFSK (Differential Frequency Shift Keying), and GMSK (Gaussian Filtered Minimum Shift Keying). More efficient modulation types typically require higher peak and/or average power to achieve the same Bit Error Rate (BER) as the above modulations. For example, PI/4 DQPSK (which is used in IS-136 TDMA cellular systems and is one of the few QPSK variants that is practical for an ambulatory medical telemetry transmitter) requires a peak to average power ratio (PAPR) of 3dB. 0.5 BT GMSK requires several dB better SNR than 0.3BT GMSK to achieve the same BER.

4) Bidirectional Transmission

The narrow 608-614 MHz band will require time division duplexing (TDD) to permit bidirectional transmission, which enables valuable telemetry command and control applications. In a practical system, T/R switch losses and additional filter insertion loss will cause 2dB of loss.

5) Time Division Multiple Access (TDMA)

TDMA is a desirable technology to apply to WMTS because of the flexibility of bandwidth allocation TDMA provides. However, a TDMA system will require a higher power level to achieve the same BER as an otherwise equivalent pure Frequency Division Multiple Access (FDMA) system: assuming the TDMA channel bandwidth is increased by the TDMA

factor, then the power must be increased by the same amount to provide the same E_b/N_0 as the FDMA system.

VitalCom performed significant research in support of its report to the Commission on behalf of this action. The results of said research indicate a radio frequency propagation and noise environment significantly more severe than indicated in modern indoor wireless design references. The causes of that environment have not been conclusively determined, but are believed to be the result of the operation of unusual equipment (e.g., x-ray, MRI, etc.), the greater concentration of safety systems and environmental control infrastructure (e.g., HVAC, radiation shielding, bio-hazard, etc.) and the unique construction requirements of health care facilities.

1. Measured Noise Floor

Recent measurements at two hospitals[26] indicate the noise floor near the center of the 608-614 MHz band (i.e. not spillover from UHF channels 36/38) is significantly above the thermal noise floor of -174 dBm/Hz. The following table has been extracted from data taken in W. Beaumont Hospital. The data was collected at 8 discrete locations utilizing a one-wavelength turntable over ten 100 kHz ranges. The maximum noise floor observed was −158dBm/Hz with an average of −164dBm/Hz (technically this is interference, but is treated as isotropic noise in design analyses).

[26] William Beaumont hospital, Royal Oak, MI; and Good Samaritan hospital, San Jose, CA.

TX SITE 2 (YELLOW)
FREQUENCY: 611 MHz
Pout @ Ant:+20 dBm
Filter No

Max Sig. Lvl [dBm]	Min Sig. Lvl. [dBm]	Noise Lvl. [dBm/Hz]
-94.74	-113.74	-165.24
-61.74	-88.24	-166.24
-84.04	-112.94	-158.44
-68.24	-90.74	-165.94
-96.24	-114.54	-162.94
-110.94	-113.44	-162.74
-30.24	-65.94	-164.64
-50.74	-94.04	-165.74

Figure 1

Additional measurements of noise (interference) which indicate significant constraints and a dependence on transmitter output power are illustrated in the following:

Figure 2) Broadband scan of good fluorescent light ballast (no noise).

Figure 3) Broadband scan of bad fluorescent light ballast.

Figure 4) Noise floor without gurney.

Figure 5) Noise floor with gurney rolling past receiver.

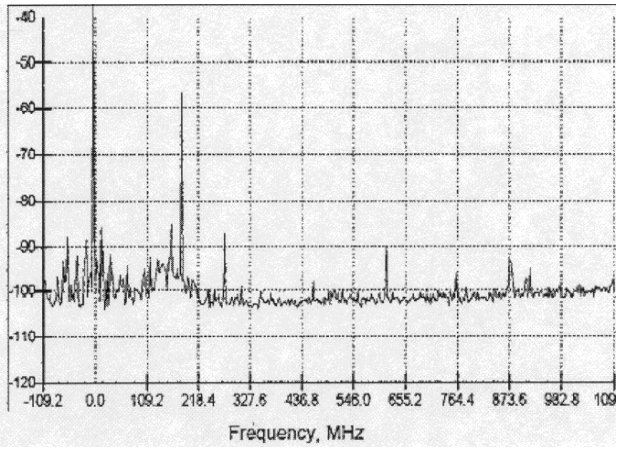

Figure 2

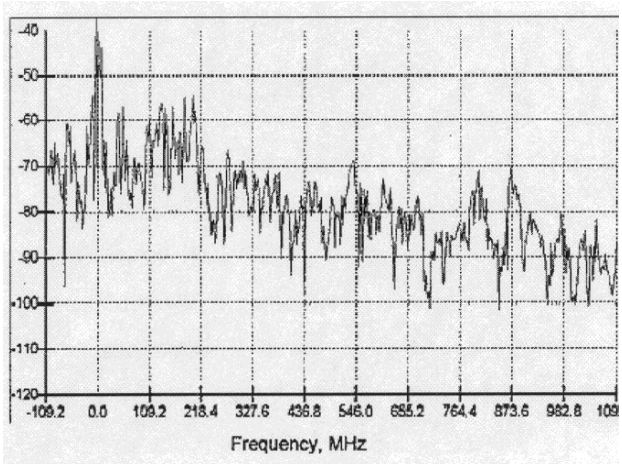

Figure 3

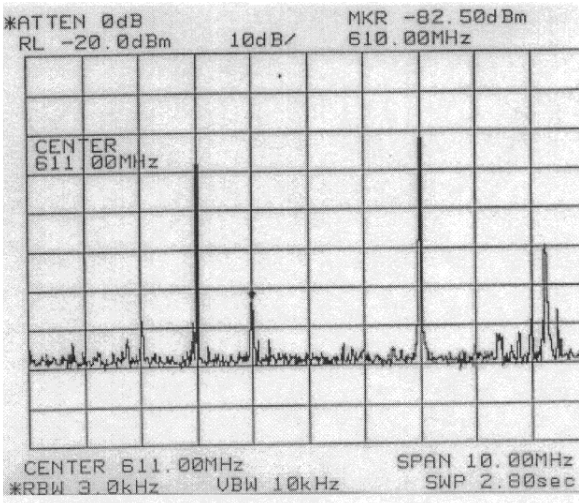

Figure 4

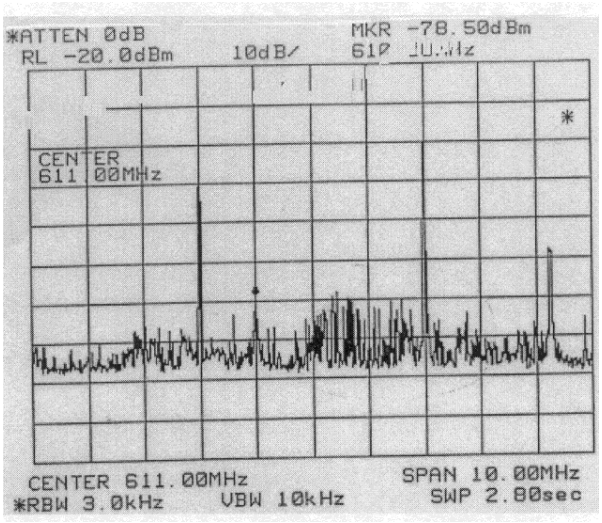

Figure 5

2. Measured Multipath Fading

Multipath fading, local to the telemetry transmitter (i.e. within a one-wavelength radius of the nominal transmitter position) often exceed 25dB and are rarely less than 10dB. In regular 900MHz Cellular Communications, fades of 20dB are common and even 30dB fades can be expected[27]. From the data presented in Figure 1 it can be seen that fades in a hospital environment can be as deep as 44dB. Figures 6 and 7 (below) show typical fades in two different locations within one hospital.

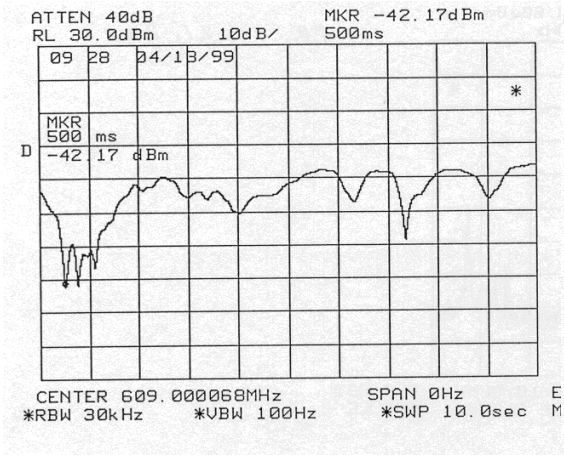

Figure 6

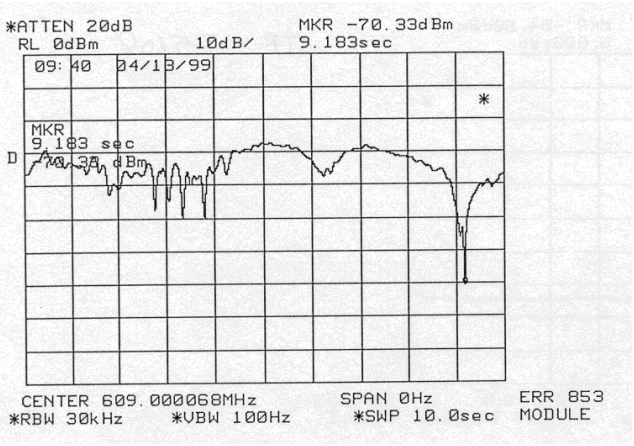

Figure 7

[27] Radio System Design for Telecommunications – Roger Freeman

3. Measured Body Absorption

Body absorption through the torso ranges from 10 to 20 dB at 611 MHz for a transmitter in the normal chest-worn position. This is consistent with Scanlon's analytic results[28]. The following figure is chest height data taken of a small, average weight Asian woman. Larger and heavier subjects are substantially worse.

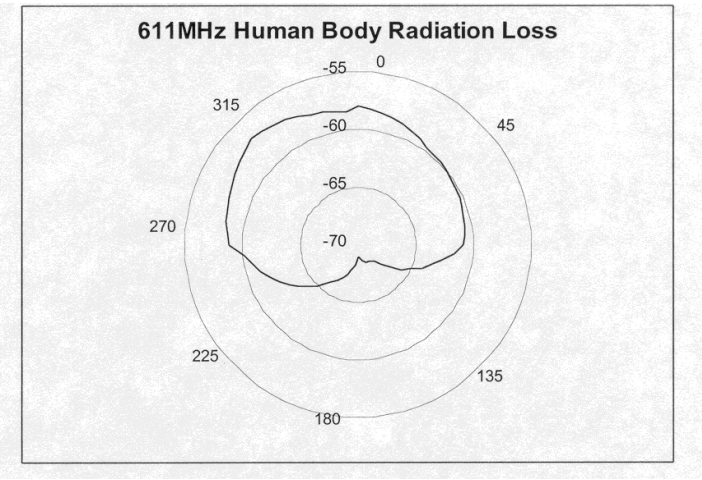

Figure 8

Summary

VitalCom's extensions to the Commission's recommended rule for operations in the 608 – 614 MHz band (§ 95.1119), in conjunction with the frequency coordination function (§ 95.1111), provide sufficient radio astronomy protection for the WMTS to use a 370 mV/m field strength.

VitalCom's analyses indicate that the presence of deep fades, the elevated noise level and the level of "cluttering" encountered in a health care facility, contribute to make up a system very

[28] Scanlon, W.G., Evans, N.E., "Body Surface Mounted Antenna Modeling for Biotelemetry Using FDTD with Homogeneous, Two and Three Layer Phantoms," Northern Ireland Bio-Engineering Centre and University of Ulster, UK.

dependent on the transmitter output power. Based on the character of the presented noise data, this conclusion is independent of the transmission method (e.g., narrowband, wideband, etc.).

VitalCom's research indicates a significant cost advantage is available to the majority of health care facilities through the approximate 5 dB increase in power recommended.

VitalCom therefore recommends that higher power operations be authorized.